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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,575	04/13/2001	Arthur Lander	82351.0003	9101

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1643

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/807,575	Applicant(s) LANDER ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/20/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

1. Please note the Examiner of record has changed. Contact information is provided at the close of the action.

Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1-6 to the extent the binding molecule binds to glypican-1) in the reply filed on 07/20/2005 is acknowledged.
3. Claims 1-12 are pending.
Claims 7-12, drawn to non-elected inventions are withdrawn from examination.
Claims 1-6 are examined on the merits to the extent the binding molecule bind to glypican-1.

Claim Objections

4. Claims 1, 4 and 5 are objected to because of the following informalities:
(a) claims 1 and 4 reference non-elected subject matter, namely binding molecules or antibodies that bind syndecan-1, respectively;
and (b) claim 5, line 4 recites glypican 1 instead of glypican-1, which has been cited in the other examined claims. Applicants' claims should consistently recite the same language. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 5 broadly claim an agent comprising a molecule that binds or affects glypican-1. The written description in this instant case only sets forth a glypican-1 antibody. The written description is not commensurate in scope with claims drawn to any molecule that binds glypican-1. Both claims read on a multitude of substances.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of glypican-1 antibodies and corresponding antigen binding fragments, the skilled artisan cannot envision the detailed structure or function of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of glypican-1 antibodies and not arbitrary substances that bind glypican-1. The specification does not evidence the possession of all the possible molecules that are embraced by the broad claims. There is insufficient support the generic claims as provided by the Interim

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Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994).

Karthikeyan discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 3213, "Preparation of antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 3216, column 1, paragraph before "In situ..." section and Figure 5. It is reasonable to conclude that the disclosed antibody would detect glypican-1 in a body fluid.

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9. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997). Ivins discloses 343-1, an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 321, "Antipeptides..." section, last sentence. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody for immunofluorescence, thereby aiding in imaging, see page 325, paragraph before "Proteoglycan..." section. It is reasonable to conclude that the disclosed antibody would detect glypican-1 in a body fluid.

10. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997). Liang discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 852, "Antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 852, "Electrophoresis..." section. It is reasonable to conclude that the disclosed antibody would detect glypican-1 in a body fluid.

11. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998). Litwack discloses 343-1,

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an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 77, "Expression..." section and page 85, "Anti-Peptide Antibodies" section. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody, thereby aiding in imaging, see page 85, "Immunohistochemistry" section. It is reasonable to conclude that the disclosed antibody would detect glypican-1 in a body fluid.

12. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998). Liu discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 22829, Figure 5 and the first paragraph of the "Characterization..." section. Attached to the said antibody was a biotinylated goat anti-rabbit IgG, thereby aiding in imaging, see page 22827, last two sentences of the "Western Blotting" section. It is reasonable to conclude that the disclosed antibody would detect glypican-1 in a body fluid.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

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-Kleeff et al. The cell-surface heparan sulfate proteoglycan glypican-1 regulates growth factor action in pancreatic carcinoma cells and is overexpressed in human pancreatic cancer. J. Clin. Invest. 102(9): 1662-1673, November 1998.

-Matsuda et al. Glypican-1 is overexpressed in human breast cancer and modulates the mitogenic effects of multiple heparin-binding growth factors in breast cancer cells. Cancer Research 61(14): 5562-5569, July 15, 2001.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

29 September 2005